Conclusions

For the reasons given above, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims. Applicants submit that the pending claims are in condition for allowance.

Respectfully submitted,
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the DHL Courier Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, DC 20231, on August 12, 2002.

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Marked up version of the claims showing the amendments made

1. An extended release pharmaceutical active formulation comprising;

- about 5-95% by weight pharmaceutical active provided as a capsule, tablet or pellet;

- an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

- an encasement coat comprising one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer [comprising] of polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

3. Cancelled

4. Cancelled

5. Cancelled

8. The formulation of claim [4] 1, wherein said formulation additionally comprises excipients, lubricants, binders or glidants.

17. An extended release pharmaceutical active formulation comprising;

- a capsule, tablet, pellet or bead of about 5-95% by weight pharmaceutical active[;], about 0-60% by weight pharmaceutical compression aid selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar, and about 0-50% by weight pharmaceutical extrusion aid;

- an encasement coat comprising one or more layers of a polymeric film encasing said capsule, tablet, pellet or bead, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight [plasticizer comprising] polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

18. Cancelled

20. Cancelled

25. The formulation of claim [3] 1, wherein less than about 20% of the pharmaceutical active is released in one hour when tested in a USP type 2 apparatus at 75 rpm in 900m1 simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and greater than 80% of the pharmaceutical active is released in one hour when tested in a USP type 2 apparatus at 75 rpm in 900ml simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C.

26. The formulation of claim [3] 1, wherein the tablet or pellet is made by direct compression.

29. The formulation of claim [3] 1, wherein said capsule, tablet, pellet or bead demonstrates extended release characteristics of greater than 4 hours when tested in a USP type 2 apparatus at 75 rpm in 900mls [ml] simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and demonstrates extended release characteristics of greater than 4 hours when tested in a USP type 2 apparatus at 75 rpm in 900mls [ml] simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C

31. A method for making an extended release pharmaceutical active formulation comprising;

[-- compressing about 5-95% by weight pharmaceutical active into tablets, pellets or beads;

- encasing said tablets, pellets or beads in an encasement coat comprising one or more layers of a polymeric film encasing said capsule, tablet, pellet or bead, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol,]

- compressing about 5-95% by weight pharmaceutical active into a capsule, tablet or pellet with an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

- encasing said tablets, pellets or beads in an encasement coat comprising one or more layers of a polymeric film, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer of polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

32. The method of claim [29] 31, wherein said pharmaceutical compression aid is present in an amount of about 0-60% by weight and said pharmaceutical extrusion aid is present in an amount of about 0-50% by weight.